510(k) Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.
The assigned 510(K) Number is **K072369**.

MAR 21 2008

Date: March 19, 2008

1. Submitter:

Submitted by:	HMD Biomedical LLC 8855 Grissom Pkwy Titusville, FL. 32780
Contact:	Merrell Shye Phone: 321-267-9911 Fax: 321-267-5582

2. Device:

Propriety Name	Evolution™ Blood Glucose Test System
Common Name	Blood Glucose Test System
Classification Name:	System, test, blood glucose, over the counter Glucose Oxidase Single (specified) analyte controls
Classification:	Class II, 21 CFR 862.1345,
Product Code:	NBW, CGA, JJX

3. Predicate Device:

We claim substantial equivalence to the LifeScan
One Touch® Ultra ® Blood Glucose Monitoring System (K021819)
By LifeScan Inc.

4. Description:

The Evolution™ Monitor is an in vitro diagnostic device designed for measuring the concentration of glucose in whole blood, which is used with the Evolution™ Test strip.

The test principle is:
This device is an in vitro diagnostic product intended for the measurement of glucose concentration in human blood. The principle of the test replies upon a specific type of glucose in blood sample, the oxidase glucose that reacts to electrodes in the test strip. The test strip employs an electrochemical signal

generation an electrical current that will stimulate a chemical reaction. This reaction is measured by the Meter and displayed as your blood glucose result.

5. Indications for use:

Indications For Use: The Evolution™ Blood Glucose Testing System is for the quantitative measurement of the concentration of glucose in whole blood taken from the fingertip, ventral palm, dosal hand, upper arm, forearm, calf and/or thigh by diabetic patients or health care professionals as an aid in the management of diabetes. Evolution™ Blood Glucose Testing System is for in vitro diagnostic use and is not to be used for the diagnosis of diabetes or for neonatal use. Alternate site testing should be done during steady- state times when glucose is not changing rapidly.

6. Comparison of Technological Characteristics with Predicate:

The technological characteristics of the new device (EVOLUTION™) in comparison to the predicate device (OneTouch®Ultra®):
The modified EVOLUTION™ device has the same technological characteristics as the current legally marketed predicate device, OneTouch®Ultra®Blood Glucose Monitoring System (K021819) By LifeScan Inc.

7. Performance Data:

Clinical: The clinical performance evaluation using the EVOLUTION™ Blood Glucose Monitoring System components were conducted for the purpose of validating the consumer use for the user and the professional accuracy. Test results showed substantial equivalence.

Non-clinical: Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the EVOLUTION™ Blood Glucose Monitoring System with respect to the predicate device. Testing involved the verification of software requirement specifications, product requirement specifications and user interface requirement specifications from risk analysis. Pass or fail criteria were based on the specification cleared for the predicate device and results showed substantial equivalence.

8. Conclusion

The conclusion drawn from the clinical and non clinical tests is that the EVOLUTION™ Blood Glucose Monitoring System is as safe, as effective, and performs as well as the legally marketed predicate device, the ONE TOUCH® Ultra®.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

HMD Biomedical LLC
c/o Ms. Merrell Shye
8855 Grissom Parkway
Titusville, FL 32780

MAR 21 2008

Re: k072369
Trade/Device Name: HMD Evolution Blood Glucose Testing System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: March 10, 2008
Received: March 11, 2008

Dear Merrell Shye:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications of Use Statement

510(K) Number(if known): K072369
Device Number: Evolution™ Blood Glucose Test

Indications For Use: The Evolution™ Blood Glucose Testing System is for the quantitative measurement of the concentration of glucose in whole blood from the fingertip, ventral palm, dosal hand, upper arm, forearm, calf and/or thigh by diabetic patients or health care professionals as an aid in the management of diabetes. Evolution™ Blood Glucose Testing System is for in vitro diagnostic use and is not to be used for the diagnosis of diabetes or for neonatal use. Alternate site testing should be done during steady- state times when glucose is not changing rapidly.

Prescription Use ___X___	AND / OR	Over-the-Counter Use___X___
(Part 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K072369